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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/761,634 | 01/21/2004 | Raghavan Rajagopalan | MRD-69DV (1485.1 US) | 3347 |
| 27805 | 7590 | 03/17/2008 | | |
| THOMPSON HINE L.L.P. Intellectual Property Group P.O. BOX 8801 DAYTON, OH 45401-8801 | | | EXAMINER SAUNDERS, DAVID A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1644 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/761,634

Applicant(s)

RAJAGOPALAN ET AL.

Examiner

David A. Saunders

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 17, 19-21, 30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 17, 19-21, 30 and 31 is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

AMENDMENT ENTRY

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of 1/25/08 has been entered. Claims 1-7, 17, 19-21 and 30-31 are pending. Claims 1-7, 17, 19-21 and 30-31 are under examination. The amendment has entered no new matter.

In order to clarify the record, it is to be noted that the claims filed on 1/25/08 have been marked with the assumption that the after FINAL amendment of 10/25/07 has been entered. In order to enhance prosecution, the examiner has approved the entry of the amendment of 10/25/07.

OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment of 10/25/07 has overcome previously stated issues as follows (these were noted in the advisory action of 11/20/07):

The objection to claim 17.

The rejection of claim 1 under 35 USC 112, 2nd paragraph, pertaining to step g).

The rejection of claim 17 under 35 USC 112, 2nd paragraph.

The rejection of claim 1 under 35 USC 112, 1st paragraph, pertaining to step d).

The rejection of claim 1 under 35 USC 112, 1st paragraph, pertaining to step e).

The amendment of 1/25/08 has overcome previously stated issues as follows:

The rejection of claim 1 under 35 USC 112, 2nd paragraph, pertaining to step g).

The rejection of claim 2 under 35 USC 112, 1st paragraph.

OBJECTION(S)/REJECTION(S) OF RECORD MAINTAINED

The following rejection(s) of record are maintained or modified as follows:

The 112, first paragraph rejection of claim 7, set forth infra, has been modified from one of enablement to one of written description/new matter.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 7 recites new matter.

Specifically, applicant's original disclosure stated nothing about the tissue distribution/localization of the heat stable toxin receptor (ST receptor), except what was incorporated by reference from US Pat. 5,518,888. Therein one finds no teachings about expression of the ST receptor in lesions, necrotic regions, ischemic regions, and inflammatory regions. Also, one finds no teachings about any kinds of tumors/cancers, other than colorectal tumors/cancers.

Applicant's urgings of 1/25/08 have stated (page 4) that "As previously analyzed, at least lesions, necrotic tissues, ischemic tissues, and inflammatory tissues may contain the recited receptor, and are thus properly included in claim 7." The examiner cannot respond to this argument, because no such conclusion was "previously analyzed". The examiner finds no such analysis was presented in the after FINAL response of 10/25/07, to the enablement rejection of claim 7. This rejection was first stated in the action of 7/26/07, after applicant's amendment of 4/27/07 narrowed the scope of the receptor of claim 1 to, specifically, the heat stable toxin (ST) receptor.

Further, even if it had been previously argued that, "at least lesions, necrotic tissues, ischemic tissues, and inflammatory tissues may contain the recited receptor, and are thus properly included in claim 7", the argument would be unconvincing. Such an argument might be convincing that the recited tissues can be properly included in

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claim 7 with respect to enablement; however, such an argument cannot be convincing that the recited tissues can be properly included in claim 7 with respect to written description. Applicant is stuck with what his original disclosure incorporated by reference from US Pat. 5,518,888. All that one finds therein is a teaching of ST receptors as being expressed in colorectal tumors/cancers. Recitation of any other tissues constitutes new matter. Recitation of tissues of broader scope (e.g. a generic tumor/cancer) constitutes new matter.

Applicant's urgings filed on 1/25/08 have been considered but are not persuasive for the above reasons.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 3/3/08 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644